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TOTAL TEMPOROMANDIBULAR JOINT (TMJ) REPLACEMENT SYSTEM
Essential Prescribing Information (EPI)

DESCRIPTION:
The Total Temporomandibular Joint (TMJ) Replacement System is implanted in the jaw to functionally reconstruct a diseased and/or damaged temporomandibular joint. The Total TMJ Replacement System is a two component system comprised of mandibular condyle and glenoid fossa components. Both components are available in multiple sizes as right and left side specific designs and are attached to bone by screws. DO NOT USE THE INDIVIDUAL COMPONENTS FOR PARTIAL JOINT RECONSTRUCTION.

MATERIALS:
Mandibular Component – Cobalt-Chromium-Molydenum (Co-Cr-Mo) alloy with titanium alloy coating
Fossa Component – UHMWPE
Screws – Titanium alloy

INDICATIONS:
The Total TMJ Replacement System is indicated for use in cases of:
1. arthritic conditions: osteoarthritis, rheumatoid arthritis, or traumatic arthritis
2. malignancy (e.g. post-tumor excision)
3. benign neoplasms
4. functional deformity
5. revision procedures where other treatments (e.g. alloplastic reconstruction, autogenous grafts) have failed
6. avascular necrosis
7. ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation
8. degenerated or resorbed joints with severe anatomic discrepancies
9. fracture
10. multiple operated joints
11. developmental abnormality

CONTRAINDICATIONS:
1. Active or chronic infection.
2. Patient conditions where there is insufficient quantity or quality of bone to support the components.
3. Systemic disease with increased susceptibility to infection.
4. Patients with extensive perforations in the mandibular fossa and/or bony deficiencies in the articular eminence or zygomatic arch that would severely comprise support for the artificial fossa component.
5. Partial TMJ joint reconstruction.
6. Known allergic reaction to any materials used in the components.

NOTE: Patients with known or suspected nickel sensitivity should not have Co-Cr-Mo devices implanted since this material contains nickel.

7. Patients with mental or neurological conditions who are unwilling or unable to follow postoperative care instructions.
8. Skeletally immature patients.
9. Patients with severe hyper-functional habits (e.g. clenching, grinding etc.)

WARNINGS:

The following risks are associated with the use of a total TMJ system.

1. Implant loosening or displacement can occur.
2. The screws used to anchor the implant may loosen causing changes in bite, difficulty in chewing, limited joint function and/or unpredictable wear on implant components.
3. Implant breakdown may result in erosion or resorption of the glenoid fossa, which may result in intense pain.
4. A foreign body reaction may occur resulting in implant deterioration and migration of materials.
5. If the implant is not properly sterilized, infection may result.
6. If the implant materials are unable to withstand the forces or pressure placed on the implant, the implant can be torn, worn, perforated, fragmented, fatigued, or fractured resulting in failure of the device to function properly.
7. Degenerative changes within the joint surfaces and components of the TMJ due to implant breakdown may result in chronic pain.
8. Degenerative changes in the joint cartilage and/or bone from disease or previous implants may lead to failure of this device.
9. If the implant materials are subject to the production of particles or corrosion, toxic elements may migrate to various parts of the body.
10. Placement of the implant in one joint only may result in harmful effects to the joint on the opposite side.
11. Placement of the implant may produce an improper relationship between the teeth surfaces that should contact during biting.
12. Implant breakdown may cause bony erosion, heterotopic bone formation, or reactive bone within the joint.
13. Use of implants may result in tinnitus or other ear problems.
14. Limited range of motion and chronic pain may continue after total TMJ surgery.
15. Infection which may result in implant removal.
16. Damage to the facial and/or trigeminal nerve with temporary or permanent paralysis of the facial muscle and/or loss of feeling in the chin, teeth, tongue, or lower jaw may occur.

The surgeon must be thoroughly knowledgeable with the components, instruments and surgical procedure. In all cases sound medical practice is to be followed and the surgeon must select the type of device appropriate for treatment. Existing mandibular and/or zygomatic arch screws or screw holes may compromise fixation. The Total TMJ Replacement System is designed for total joint reconstruction and components are to be used as a system. Do not use the individual components for partial joint reconstruction.

The patient is to be warned that the system does not replace normal healthy bone in their TMJ and they may continue to have chronic pain and limited range of motion. The system can break or loosen as a result of stress, activity, or trauma. Patients with severe hyper-functional habits may have an undesirable outcome. The patient is to be made aware of surgical risks and possible

adverse effects prior to surgery and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

PRECAUTIONS:

1. DO NOT USE if there is loss of sterility of the devices.
2. DO NOT USE opened or damaged implants and only use implants that are packaged in unopened or undamaged containers.
3. DO NOT USE the individual components of this total system (e.g. mandibular components, fossa components, or screws) for partial joint reconstruction.
4. Infection can lead to failure and subsequent removal of the devices.
5. Damage to the implant can occur as a result of traumatic injury or excessive activity.
6. Neurovascular injuries can occur due to surgical trauma.
7. Metal sensitivity or foreign body reaction can occur due to the device materials or materials from previously implanted devices.
8. Implant breakdown and/or degenerative changes in the TMJ may cause pain, which may lead to re-operation.
9. Use of the system with filler material:
   The fossa component may be used with a filler material when it is desired to fill voids between the fossa prosthesis and the glenoid fossa bone. The filler should never be used for fixation of the device or in any load bearing application. If a filler is used in the fossa region, screws are placed after polymerization of the filling material, if applicable. Use of any legally marketed craniomaxillofacial filler material is recommended.

INSTRUMENTATION PRECAUTIONS:

Specialized instruments are designed for use with the Total TMJ Replacement System to aid in the accurate implantation of the components. Intra-operative fracture or breakage of instruments can occur. Instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. W. Lorenz recommends that all instruments be regularly inspected for wear and disfigurement.

ADVERSE EVENTS:

Adverse events reported throughout the duration of an approved Food and Drug Administration (FDA) clinical study implanting the Total TMJ Replacement System are summarized as the following. See Tables 6 and 7 for more detailed information

- Removal of components(s)
- Infection (systemic or superficial)
- Facial swelling and/or pain
- Facial nerve dysfunction
- Excision of tissue
- Heterotopic bone formation
- Neuroma formation
- Ear problems
- Dislocation

CLINICAL STUDIES:
A prospective clinical study began in the United States in 1995 and was designed to document patient outcomes after implantation of the Total TMJ Replacement System. Unilateral and bilateral patients were enrolled only after non-surgical treatment and/or previous implant failure.

A total of 180 cases received 268 joints. Overall patients demonstrated decrease pain, increase function, increase in maximal incisal opening (MIO), and satisfaction with their outcome. See the following Tables 1-7, which summarize the clinical outcome.

TABLE 1
Jaw Pain Intensity

Visual Analog Scale (0 = none, 10 = most intense pain imaginable)										
Jaw Pain	Pre-op n=180	1 mo. n=170	3 mo. n=153	6 mo. n=143	1 yr n=116	1.5 yr n=89	3 yrs n=45	4 yrs n=22	5 yrs n=4	6 yrs n=5
Mean	**8.1**	**4.3**	**3.6**	**3.1**	**2.9**	**3.4**	**2.6**	**3.2**	**2.6**	**2.9**
No data	0	9	17	15	19	17	10	1	5	3
Death/ Removal	0	1	1	2	3	3	2	0	1	1
Total n possible	180	180	171	160	138	109	57	23	10	9

TABLE 2
Interference with Eating

Visual Analog Scale (0 = none, 10 = excruciating)										
Interference with Eating	Pre-op n=180	1 mo. n=170	3 mo. n=153	6 mo. n=143	1 yr n=116	1.5 yr n=89	3 yrs n=45	4 yrs n=22	5 yrs n=4	6 yrs n=5
Mean	**8.0**	**4.5**	**3.4**	**3.0**	**2.8**	**3.0**	**2.5**	**3.5**	**3.2**	**3.0**
No data	0	9	17	15	19	17	10	1	5	3
Death/ Removal	0	1	1	2	3	3	2	0	1	1
Total n possible	180	180	171	160	138	109	57	23	10	9

TABLE 3
Maximal Incisal Opening (MIO)

Measured in millimeters (mm)										
MIO	Pre-op n=180	1 mo. n=170	3 mo. n=153	6 mo. n=143	1 yr n=116	1.5 yr n=89	3 yrs n=45	4 yrs n=22	5 yrs n=4	6 yrs n=5
Mean	**19.2**	**25.0**	**29.2**	**30.1**	**30.7**	**30.7**	**29.8**	**30.3**	**28.5**	**26.6**
No data	0	9	17	15	19	17	10	1	5	4
Death/ Removal	0	1	1	2	3	3	2	0	1	1
Total n possible	180	180	171	160	138	109	57	23	10	9

TABLE 4

Patient Satisfaction (* includes enthusiastic, very satisfied, and satisfied)

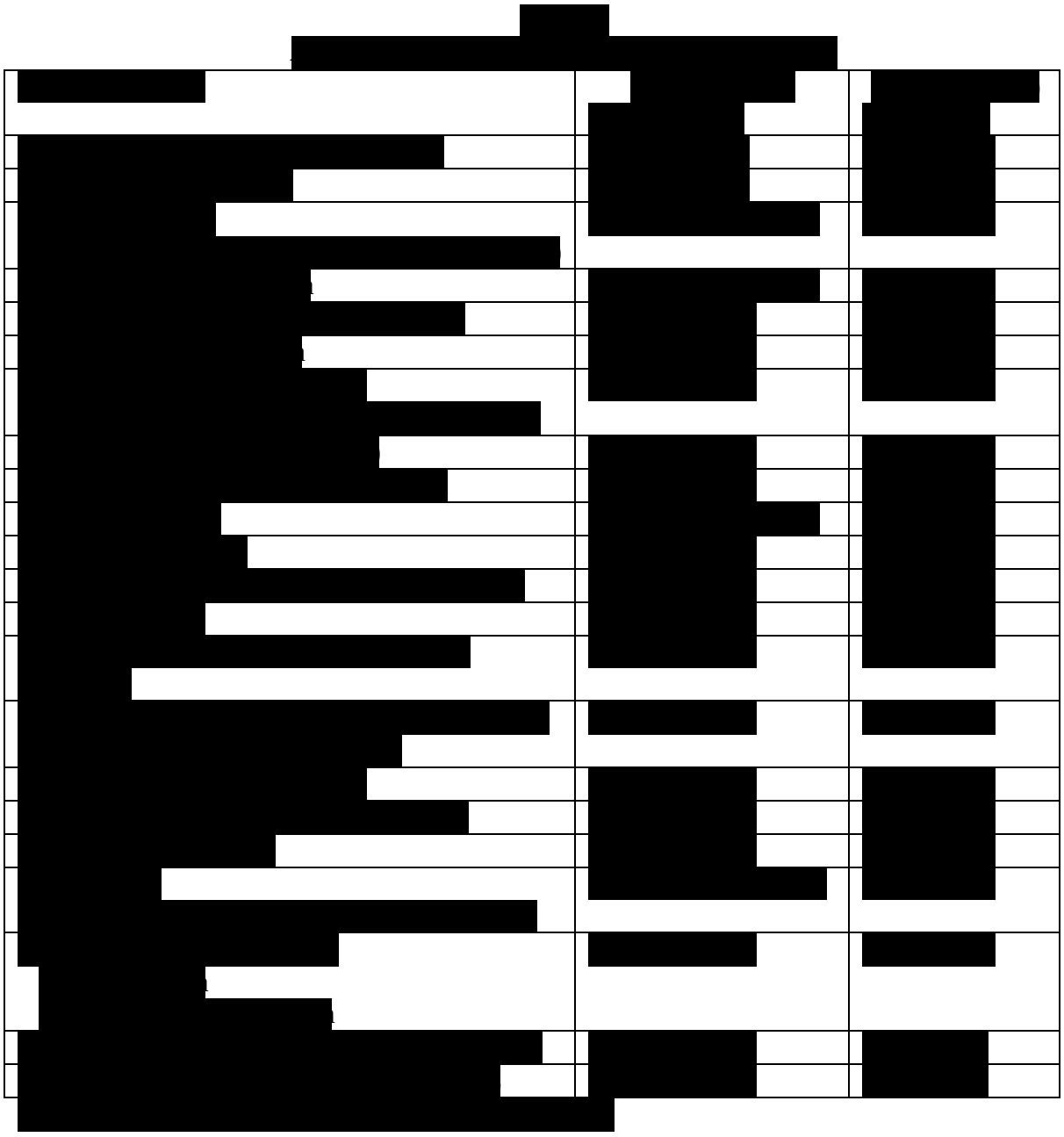
% of joints	1 mo. n=236	3 mo. n=212	6 mo. n=193	1 yr n=156	1.5 yr n=119	3 yrs n=58	4 yrs n=25	5 yrs n=5	6 yrs n=8
Satisfied* Or better	**97%**	**95%**	**95%**	**96%**	**97%**	**98%**	**100 %**	**100 %**	**100 %**
No data	11	25	20	17	21	9	3	8	4
Death/ Removal	1	1	3	3	4	2	1	0	1
Total n possible	248	238	216	176	144	69	29	13	13

Table 5

In Hindsight, Would You Choose to Have This Surgery?

% of patients	1 mo. n=170	3 mo. n=153	6 mo. n=143	1 year n=116	1.5 year n=89	3 years n=45	4 years n=22	5 years n=4	6 years n=5
Yes %	168 **99%**	148 **97%**	140 **98%**	112 **97%**	84 **95%**	44 **98%**	20 **91%**	4 **100%**	5 **100%**
Unsure	0	0	0	0	0	1	0	0	0
No data	9	17	15	19	17	10	1	5	4
LTF[1]	1	1	2	3	3	2	0	1	1
Total n possible	180	171	160	138	109	57	23	10	9

[1] LTF = Lost to follow-up (either death or permanent removal of all components)



INDIVIDUALIZATION OF TREATMENT:
Do not use in children. The Total TMJ Replacement was designed for use in skeletally mature patients.

PATIENT COUNSELING INFORMATION:
Discussion of the following points is recommended prior to surgery.

- The importance of prompt medical attention if they experience unusual swelling in the area of the implant.
- The risks associated with a total TMJ system (see Warnings and Adverse Events).
- Post-operative pain relief and return of function varies from patient to patient.
- Additional treatment may be required including but not limited to extended physical therapy, bite splint, dental braces, and/or orthognathic and reconstructive surgery .

HOW SUPPLIED:
The Total TMJ Replacement System mandibular and fossa components are supplied sterile in individual packages. Screws, trials, and instruments are supplied non-sterile and must be sterilized prior to surgical use. See the following autoclave recommendations under Sterility.

INSTRUCTIONS FOR USE:
A detailed Surgical Technique is available describing implantation of the components.

REUSABLE INSTRUMENT CLEANING METHOD

1. Disassemble reusable instruments from powered hand piece (powered hand pieces not supplied by Lorenz). Clean reusable instruments within two hours after being used in surgical application.
2. Pre-clean
   Remove gross contamination by hand under running water using a mechanical aid (e.g. brush). Wear protective gloves and goggles.
3. Pre-wash Cycle
   After visually removing gross contamination, clean using an automatic washer unit using a thermal ultrasonic cycle or a continuous tunnel process. Automatic washer equipment should be operated as instructed by the manufacturer of the washer unit.
   Minimum cycle parameters: 4 minutes at 49° C or 120 ° F
4. Wash Cycle
   Use detergent per manufacturer's instructions.
   Minimum cycle parameters: 12 minutes at 49° C or 120 ° F
5. Final Rinse
   After washing, reusable instruments are rinsed with deionized water for a minimum of 4 minutes at 49° C or 120 ° F. Reusable instruments should be placed in the instrument tray.

Warning: Do not reuse titanium screws under any condition. Discard screws that were applied to the patient and removed. Do not reuse screws that entered the operative site.

STERILITY:
The Total Temporomandibular Joint Replacement System mandibular and fossa components are sterilized by exposure to a minimum of 25 kGy of gamma irradiation. DO NOT RESTERILIZE.

Screws, trials, and instruments are supplied non-sterile.
The following autoclave recommendations are for sterilization of screws, trials, instruments, and containers used with the Total TMJ Replacement System.

Pre-Vacuum Steam Sterilization:
Temperature: 270º - 275º F (133º - 135º C)
Time: Fifteen (15 minutes
Drying Time: Eight (8) minutes

Since Walter Lorenz Surgical, Inc. is not familiar with individual handling methods, cleaning methods and bioburden, Walter Lorenz Surgical, Inc. cannot assume responsibility for sterility even when the above guidelines are followed.

CAUTION:
Federal Law (USA) restricts this device to sale, distribution, or use, by or on the order of a physician.

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